

REMARKS

Reconsideration of the present application in view of the above amendments and the following remarks is respectfully requested.

I. Status of the Claims

Claims 104-170 are pending in this application. Claims 128-136 have been canceled, claims 104, 110, 111, 113, 115, 116, 118, 120, 121, 123, 124, 126, 127, 138, 140, 141, 143, 145, and 146 have been previously amended. Claims 104, 106, 108, 111, 124, 153, 157, 167 and 169 are currently amended. The Examiner has withdrawn the objection to claims 109-110, 122-123, 125-126, 128-136 under 35 U.S.C. § 132 and to claims 109-123 and 125-146 35 U.S.C. § 112.

II. Interview with Examiner

The Examiners granted Applicants a telephone interview on August 10, 2004. Applicants thank the Examiners for extending this courtesy.

III. Rejection Under 35 U.S.C. § 103

The Examiner has rejected claims 104-112, 114, 117, 119, 124-127, 137, 139, 142 and 144 under 35 U.S.C. § 103(a) as being unpatentable over Brown, United States Patent No. 5,951,300, (“Brown300”) in view of Alyfuku, et al., United States Patent No. 5,410,471, (“Alyfuku”).

With respect to claims 104 and 124, the independent claims pending from this group, the Examiner states that Brown300 teaches a method for assisting an individual to monitor, control and modify certain aspects of the individual's physiological status according to a preset physiological status goal, the method comprising establishing the physiological status goal according to certain preselected physiological parameters of the individual, using data indicative of one or more measured parameters to compare target parameters to actual parameters, and providing status information and/or a treatment plan to the individual.

The Examiner states that Brown300 does not explicitly disclose wearing a wearable physiological monitoring device on the body of the individual and generating data indicative of one or more measured parameter of the individuals using the device; however, the Examiner cites Alyfuku as teaching the affixing of a physiological monitoring device in proximity to the body of the individual and generating data indicative of one or more measured parameters of the individual using the device. The Examiner concludes that it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method disclosed in Brown300 to include wearing a wearable physiological monitoring device on the body of the individual and generating data indicative of one or more measured parameters of the individual using the device as taught by Alyfuku to provide a networked vital information health monitoring system that is capable of passive detection of vital signs.

The Examiner's characterization of the Brown300 reference is misplaced. The reference is directed to a system which is entirely focused on the coordinated, combined display of health related information in conjunction with certain entertainment, advertising and/or other programming material (*Brown300*, Col. 3, Lines 8-10, 13-15). More specifically, the system incorporates a computer or other device operating a conventional browser for observing or

interacting with material found on the Internet (*Id.*, Col. 3, Lines 28-34). The system generates a composite Web page of health related information, entertainment information and other undesirable content, with each subject accorded a certain amount of space on the generated page based on the input of the user (*Id.*, Col. 4, Lines 54-65; Col. 5, Lines 2-8).

Brown300 discusses a criticality index which is a measurement of a patient's compliance with a prescribed treatment regimen and which also modulates the amount and size of health-related sections displayed on the viewed page by the user. (*Id.*, Col. 5, Lines 21-25). A user inputs goals, as prescribed by a doctor or other health professional, into the system, which are stored for comparison to later reported data. If a user is not in compliance with a doctor-prescribed regimen, the system interprets the criticality index to modify the browser display such that the preprogrammed health content will comprise a substantial amount of the page. If the user is at or near compliance, the health content displayed on the page will not be nonexistent, but it will be somewhat less than if the user is not in compliance. (*Id.*, Col. 5, Lines 21-37).

The Brown300 reference contemplates, but does not disclose, manual input by the user (*Id.*, Col. 6, lines 35-45). Further, the Brown300 reference specifically states that the health information output is a series of preformatted segments of text or other information (*Id.*, Col 5, Lines 45-50). There is no teaching or suggestion in Brown300 of any output of the actual measured physiological parameters or other quantitative data relating to the user. Accordingly, the Brown300 reference may make a quantitative calculation of the relationship of the user's physiological data to the goal, but does not report any such information to the user. Instead, the modification or change in the Brown300 system output based on the user data is restricted to the ratio of health related information to entertainment related information displayed in the browser window. Therefore, the manual input of the user in Brown300 is utilized only for the system's

internal assessment of the status of the user in comparison to the preset physiological goals of the user, information that may not be current if the user is not consistent with the appropriate measurements. As a result, Brown300 does not provide feedback to the user of a quantitative or qualitative assessment of where the user stands in relation to those goals.

Regardless of whether the physiological goals of the user have been met, some health content will still be displayed even if the user has met the preset goal. Further, because the content is not specific with regard to actual degree of achievement, the user has no way of knowing whether and to what degree, qualitatively, they are in compliance. In this regard, Brown300 clearly anticipates the need for data input by the user for the determination of the criticality index and contemplates the stated desire of personalized educational health content being provided to the user (*Id.*, Col. 1, line 23). However, Brown300 specifically omits from its core functionality any feedback to the user regarding the progress of the user toward the goals.

The Examiner cites Alyfuku for the functionality of a wearable monitoring device and the generation of data indicative of measured parameters. Alyfuku is directed toward the passive monitoring of a user's physiological information by providing a highly specialized and localized environment in which the user **must** be located in order for the data to be gathered. (*Alyfuku*, Col. 10, Lines 33-44). Alyfuku requires that the user engage with certain highly specialized appliances in order to have the measurements taken. Furthermore, the measurements are taken only during the relatively brief time period that the user is physically in contact with the appropriate measuring device, each of which is permanently mounted within the specialized living space.

While Applicant concedes that the finger cuff of the sphygmomanometer identified by the Examiner is "worn" by the user, this relatively incidental contact is more akin to the casual

interaction of the user with the tub or toilet, rather than the wearing of a monitoring device or article of clothing. Furthermore, Alyfuku teaches that household testing and measurement systems **ensure** monitoring of the latest information because such measurement **at home** may be carried out more readily and frequently. Alyfuku states that measurements may be performed under adequately **relaxed conditions** while the user is engaging in regular daily activities using the appropriately equipped household items (*Id.*, Col. 2, Lines 37-40). However, such ensuring necessitates the use of fixed devices and teaches away from use while the user is in motion or under any type of daily activity-related stress and also from a wearable device that monitors subject parameters under ordinary life conditions.

Neither Brown300 nor Alyfuku provide a wearable physiological monitoring device which is utilized to provide status information indicative of the relative degree of achievement of the user's performance with relation to a goal as required by claims 104 and 124. The combination of the two references is equally inapposite. As stated in the previous response, the Federal Circuit has held that "[w]hen a rejection depends on a combination of prior references, there must be some teaching, suggestion, or motivation to combine the references." *In re Rouffet*, 149 F.3d 1350, 1355. In accord with these principles, Applicants respectfully submit that if the Examiner were to reject claims 104 and 124 under 35 U.S.C. § 103(a) by combining Brown300 with Alyfuku the Examiner would be using the claimed invention as a blueprint to piece together prior art elements to defeat the patentability of the invention claimed in claims 104 and 124, which is improper.

With respect to *In re Rouffet*, while Brown300 anticipates the need for data input by the user, there is no teaching or suggestion regarding the automated input of such information, even though a number of computer or other devices capable of such automatic calculation are

described therein. There is no teaching or suggestion in the Brown300 reference of any **stated need or desire** to provide **quantitative** output to the user which embodies the degree to which the user has complied with a routine to achieve a stated, measurable goal. Brown300 merely provides for the delivery of varying amounts of health content in the form of articles, informational and/or motivational messages in addition to entertainment content and advertising based on the user's reasons for using the system as opposed to the user's progress. (*Brown300*, Col. 4, Lines 29 - 41; Col. 6, Lines 10-25).

The system as described in Alyfuku may be provided with an LCD to display measured results. However, the results that are displayed are mere output as measured by the device or are the result of simple calculations. Alyfuku does not disclose establishing preset goals of the user and, accordingly, does not teach or suggest the comparison of the target parameters to actual measured parameters for the determination of quantitative or qualitative status information and associated relative degree of achievement of the user. (*Alyfuku*, Col. 9, Lines 51 to Col. 10, Line 22; Col. 19, Lines 40-49; Col. 24, Lines 42-44; Col. 25, Lines 48-53; Col. 26, Lines 5-9; Col. 27, Lines 15-21;).

Moreover, the pending claims in the instant application differ from Brown300 and Alyfuku in that they are directed toward providing the user's current quantitative goal status and relative degree of achievement of that goal. The wearable physiological monitoring device as defined and described in the specification also differentiates Brown300 and Alyfuku because the device is worn on the body which Alyfuku and Brown300 clearly do not contemplate, as Alyfuku is specifically directed to incidental contact with the measuring devices while the user is essentially at rest.

The quantitative data of the claimed invention is used for a variety of categories including nutrition, activity level, mind centering, sleep, daily activities and how the user feels as described in the specification. Quantitative data is described as being displayed for each category in the form of personalized feedback specifically based on the user's measured parameters. The feedback may be presented as suggestions to refine the daily routine of the individual and may be customized based on information learned about the user during the user's registration. The feedback may also be in a graphical or chart format such as a bar graph with the health, wellness and lifestyle indicators having an associated piston that indicates how well the user is performing in each of the categories stated categories. With respect to the customized feedback and graphically formatted output, the pending claims address the current invention's ability to maximize the likelihood that the user will implement and maintain a healthy lifestyle because it provides a current and accurate assessment of the user's achievement status and addresses the user's barriers to goal attainment (*See Application*, Page 4, Lines 15-18; Page 5, Lines 2-11; Page 22, Lines 15-21; Page 24, Lines 17-21; Page 25, Lines 8-10; Page 26, Lines 13-17; Page 26, Lines 14-17; Page 27, Lines 4-6; Page 28, Lines 19-22; Page 29, Lines 5-7, 13-17; Page 30, Lines 3-5; Page 33, Lines 10-14; Page 34, Lines 4-14, Lines 21-23).

The Examiner has rejected claims 109-112, 114, 117, 125-127, 137, 139, 142 and 144 on the basis that Brown300 and Alyfuku teach a method as analyzed and discussed in claims 104 and 124 wherein at least two sensors selected from a group of physiological and contextual sensors generate data indicative of at least a first and second parameter of said individual, said generating step further comprising generating derived data that is used to determine said status information and relative degree of achievement relating to at least one of activity level, sleep, nutrition, stress level and relaxation level.

Applicant respectfully disagrees that the data of Alyfuku is derived data as required by the pending claims. For example, Alyfuku compares stored vital information to current vital information to verify the identity of the individual on the measuring device. (*Alyfuku*, Col. 23, Lines 5-12). With respect to the bathtub, this verification is performed through the derivation of the volume of water displaced by the bather in the tub by the detection of the initial level of water in the tub when the bather entered and comparison to an average level of water displacement that is stored in the measuring device (*Alyfuku*, Col. 23, Lines 12-31).

Applicant's method provides for the generation of data indicative of various physiological parameters such as heart rate, pulse rate, beat-to-beat heart variability and EKG. This data can be generated by the appropriate sensor associated with the physiological monitoring device. Based on this data, data can be derived with respect to non-measurable information such as ovulation, maximum oxygen consumption rate, or stress level.

The Examiner has rejected claims 113, 118, 138, 143, 149, 152-153, 157, 167-170 under 35 U.S.C. § 103(a) as being unpatentable over Brown300, in view of Alyfuku and further in view of Korenman, et al., United States Patent No. 6,067,468 ("Korenman"). With respect to claims 113, 118, 138, 143, 149, 152, 167 and 168 are dependent upon, and have the same limitations of, either of claims 104 and 124 and are distinguished for the same reasons given above.

Furthermore, the Examiner states that Brown300 and Alyfuku fail to disclose at least two sensors adapted to generate data indicative of certain physiological parameters. The Examiner cites Korenman for teaching at least two sensors to generate data indicative of certain parameters, stating that it would have been obvious to modify the method for assisting an individual of Brown300 and Alyfuku to include said at least two sensors with the motivations of testing an aspect of a user's physiological condition which provides an information display that may be

viewed by the user to provide information about the user's current condition and display an indication of the parameters measured. Korenman, however, merely teaches the use of galvanic skin resistance sensors. All of the referenced claims require the selection of at least two of the sensor types identified on the specific list included in the claim. Korneman includes a teaching of only one type of sensor contained in the list. The Examiner's reliance upon Korenman for this teaching is therefore misplaced.

The Examiner has rejected claims 115-116, 120-121, 140-141, 145-146, 154-156 and 158-166 under 35 U.S.C. § 103(a) as being unpatentable over Brown300, in view of Alyfuku, et al. and Korenman and further in view of Pottgen, et al., United States Patent No. 5,813,994 ("Pottgen") and Nasiff, United States Patent No. 4,757,453 ("Nasiff"). The Examiner cites Pottgen for a heat flux sensor which is utilized to calculate caloric output of the user. Nasiff is cited for a body motion sensor. Each of these claims contain the limitation relating to the determination of quantitative status information indicative of the relative degree of achievement of said individual's performance and the provision of such information regarding said individual as identified above with respect to claims 104 and 124. These claims are therefore distinguishable from Brown300 and Alyfuku for the same reasons given above.

Claims 122 and 123 also contain the limitation relating to the determination of quantitative status information indicative of the relative degree of achievement of said individual's performance and the provision of such information regarding said individual as identified above with respect to claims 104 and 124. These claims are therefore distinguishable from Brown300 and Alyfuku for the same reasons given above.

With respect to claims 122, the Examiner states that Brown300 and Alyfuku both fail to disclose a method further comprising the step of aggregating the data indicative of the measured

parameters with data collected from a plurality of individuals; however, it would have been obvious to modify Brown300 and Alyfuku to include a step of data aggregation as taught by Brown119 with the motivation of collecting a subset of data from the inputs to allow a reduction in the number of direct connections between the processing means and the inputs and utilizing the data aggregation means to store data for multiple patients for use in epidemiological research. With respect to claim 123, the Examiner states that the cited references when combined with Brown 310 provide the additional step of creating reports based on the aggregation of data for the purpose of statistical analysis.

Applicant agrees with the Examiner that both Brown300 and Alyfuku fail to disclose the step of aggregation and the further step of creating reports based on the same. However, neither Brown300 nor Alyfuku teach or suggest the concept of data aggregation and report generation. The references do not contemplate the collection of data for dissemination to the user or third parties for the purpose of statistical analysis or any other suitable use for such aggregated data. Therefore, there is no basis in Brown300 or Alyfuku to combine either reference with Brown119 or Brown310.

The Examiner has rejected claims 147, 148, 150 and 151 under 35 U.S.C. § 103(a) as being unpatentable over Brown300 and Alyfuku and further in view of Pottgen. The Examiner states that although Brown300 and Alyfuku fail to disclose a wearable physiological monitoring device as part of an armband or garment, Pottgen teaches a wearable physiological monitoring device that may be part of an armband or can be worn on the body with no significant limitation on motion or mobility.

It is improper to combine the Pottgen reference with the Brown300 and Alyfuku references when Brown300 does not even teach or suggest the use of a wearable physiological

monitoring device, and Alyfuku does not teach or suggest that its subject measuring devices are anything other than fixed with respect to location. These devices consist of appropriately equipped appliances and household furniture and pose significant limitations on the motion or mobility of the user. Each must be utilized in its respective fixed location, pursuant to incidental contact with the user. Alyfuku teaches that household testing and measurement systems ensure monitoring of the latest information because such measurement at home may be carried out more readily and frequently. Alyfuku states that measurements may be performed under adequately relaxed conditions while the user is engaging the appropriately equipped household items (*Alyfuku*, Col. 2, Lines 37-40), but such ensuring necessitates the use of fixed devices and teaches away from use while the user is in motion or under any type of daily activity related stress.

CONCLUSION

In light of the foregoing, claims 104-170 are in condition for allowance. Reconsideration is requested at an early date.

Respectfully submitted,

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